K024022
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BIOMET

JAN 2 3 2003

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor: Biomet Orthopedics, Inc
56 E. Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Kacy Arnold, RN, MBA
Telephone: (574) 372-1644
Fax: (574) 372-1683

Proprietary Name: Osteo-cable Sleeve

Common or Usual Name: Bone Screw

Device Classification: Screw, Fixation, Bone (888.3040)

Device Product Code: 87HWC

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Biomet's BMP™ Cable System (K982545)

Indications for Use: The Cable Sleeve is indicated for general orthopedic repairs, such as:

- Femur and Tibial Fractures
- Prophylactic banding
- Trochanteric reattachment
- Olecranon fractures
- Patella fractures
- Ankle fractures
- Fixation of spiral fractures in conjunction with I/M nailing and screwing techniques
- Sternum fixation after open heart surgery
- Stabilization of cortical onlay strut graft

Device Description: The device modified is the cable sleeve used in the Biomet's BMP™ Cable System (K982545), P/Ns 350805 and 350813/21. No other parts of this system are being modified. The device is machined from a single piece of 316 LVM stainless steel, eliminating assembly of any components. The device profile is in the shape of a wedge with two longitudinal holes that run the length of the part. The holes allow for cables to be passed through during surgery. The narrow end of the wedge has a thin plate to increase surface area. There are small spikes on the bottom of the plate to help eliminate migration of the plate.

Non-Clinical Testing: Mechanical testing demonstrated the modified device performed as well as or better than the previously marketed devices

Clinical Testing: Clinical testing was not used to establish substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2003

Ms. Kacy Arnold, RN, MBA
Regulatory Affairs Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K024022
Trade Name: Osteo-Cable Sleeve
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone Fixation Cerclage
Regulatory Class: II
Product Code: HXN and JDQ
Dated: January 14, 2003
Received: January 15, 2003

Dear Ms. Arnold:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Milhan

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known) : K024922

Device Name: Osteo-cable Sleeve

Indications for Use: The Osteo-cable Sleeve is indicated for general orthopedic repairs, such as:

- Femur And Tibial Fractures
- Prophylactic Banding
- Trochanteric Reattachment
- Olecranon Fractures
- Patella Fractures
- Ankle Fractures
- Fixation Of Spiral Fractures In Conjunction With I/M Nailing And Screwing Techniques
- Sternum Fixation After Open Heart Surgery
- Stabilization Of Cortical Onlay Strut Graft

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number 1/23/03

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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